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Basic Investigation

Directional Atherectomy With the Omnicath®: A Unique New Catheter System

Wojciech Mazur, MD, Nadir M. Ali, MD, George P. Rodgers, MD, Daryl G. Schulz, RT, Brent A. French, PhD, and Albert E. Raizner, MD

Omnicath® is a directional atherectomy catheter that employs deflecting nontraumatizing wires to anchor the cutting window at the atherectomy site. This anchoring system regulates the depth of cut and provides directional control and distal perfusion. The system continuously removes debris through a suction port from the operative site. To demonstrate the performance of the device, the Omnicath® was tested in the external iliac arteries of ten atherosclerotic Hanford miniature swine in which concentric and eccentric lesions were induced. Five animals were sacrificed 3 days after atherectomy; the remaining five animals were sacrificed 6 weeks after the procedure. The acute histology demonstrates depth of cuts varying from partial plaque removal to near full thickness removal of the arterial wall. Histologic sections of the 6 week follow-up group demonstrated minimal healing response. The anchoring wires did not induce either acute injury or neointimal proliferation in the 6 week follow-up period. In conclusion, the Omnicath® permits effective and safe atherectomy in this investigative model.

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Key words: atherectomy, peripheral vascular disease, eccentric lesion

INTRODUCTION

Directional atherectomy is an alternative and adjunct to a number of procedures intended to treat peripheral vascular disease such as percutaneous transluminal balloon angioplasty (PTA) and other atherectomy techniques including transluminal extraction and rotational ablation [1,2]. These procedures have gained acceptance since short and long term results have been encouraging [3,4], especially in the removal of short, discrete, eccentrically placed atheroma. Herein we present the short term and intermediate term performance of a novel atherectomy device in removing concentric and eccentric lesions in the external iliac arteries of Hanford miniature swine.

MATERIALS AND METHODS

The Omnicath® atherectomy catheter (Fig. 1) is a radiopaque torqueable catheter with a hollow cylindrical housing at the distal end, a longitudinal window on one side, and a unibody tripod extendible anchoring deflector wire configuration on the opposite side which serves as an anchoring pad. The cutter is activated by hand and rotated by a battery powered motor via a hollow drive shaft. The idler shaft covers a 2 cm section of the drive shaft at the distal end to minimize or eliminate the potential of tissue wrapping and binding the drive shaft. The catheter is passed transluminally over a 0.014 or 0.018 inch guidewire. Once the window is positioned over the lesion, the cutter is activated and passed across the lesion. The depth of the anchoring wire pad can be adjusted, thus regulating the depth of cutting. The atheromatous debris collects in the housing and is aspirated through a removal port at the proximal end of the catheter. The extended anchoring wire can withhold a maximum pressure of 27 PSI, above which it will collapse. This mechanism was created not only to prevent injury to the vessel wall imposed by the anchoring wire, but also to prevent vessel perforation by the cutter when deep cuts are selected. The nominal data are presented in Table I.

Animal Model

Ten Hanford miniature swine (15–25 kg) were obtained from a licensed laboratory animal supplier. All procedures and handling were performed in such a way

From the Section of Cardiology, Department of Medicine, Baylor College of Medicine and The Methodist Hospital, Houston, Texas

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Address reprint requests to Albert E. Raizner, M.D., The Methodist Hospital, 6535 Fannin MS F-100, Houston, TX 77030.

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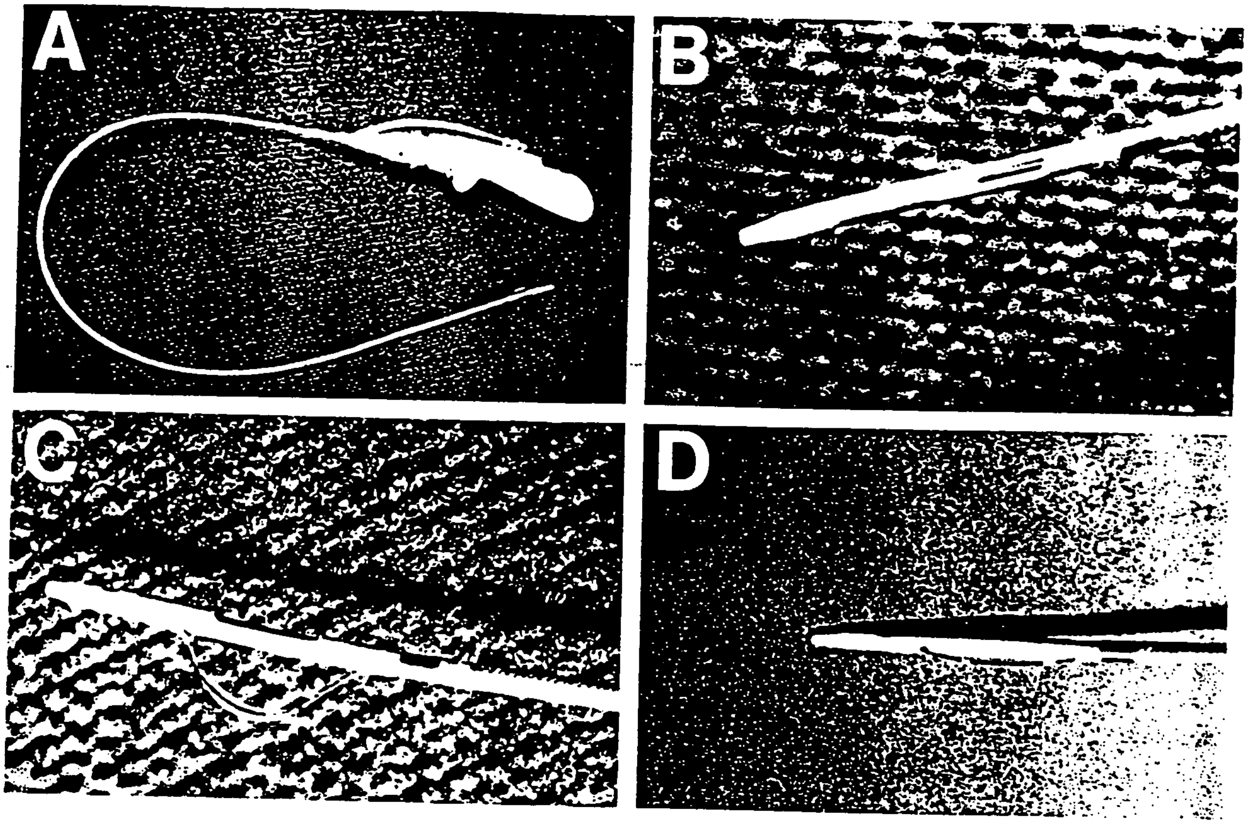

Fig. 1. A: Omnicath®. B: The window and the blade. The housing with (C) deflected and (D) collapsed anchoring wire.

TABLE I. Omnicath® Nominal Data

Catheter length	80 cm
Diameter at the housing	8.3 F
Length of the window	12 mm
Depth of the anchoring wire pad (4 degrees of extension in 1.5 mm increments)	0–6 mm
Volume of blood removed per cut	2–3 ml
Regulated depth of cut	200–800 μm
Proximal assembly ports	Suction port Guidewire port

as to minimize discomfort to the animals. The guidelines set forth by the American Physiological Society regarding animal handling were followed closely. The protocol was approved by the Institutional Animal Care and Use Committee of Baylor College of Medicine.

The animals were placed on an atherogenic diet composed of 2% cholesterol, 15% fat, and 1.5% sodium cholate. The animals were fed 3% of body weight of diet per day throughout the study.

Concentric and Eccentric Lesion Induction

One month after the atherogenic diet was started, all ten animals underwent peripheral lesion induction in both external iliac arteries. The animals were sedated

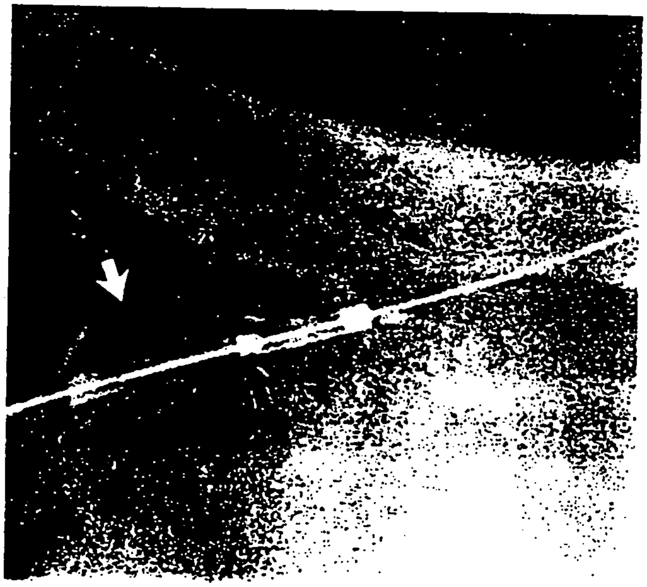

Fig. 2. Omnicath® positioned in the porcine external iliac artery. Black arrow points to the blade. White arrow indicates the deflector anchoring wire. The distal radiopaque dot enhances the intraoperative visualization of the device.

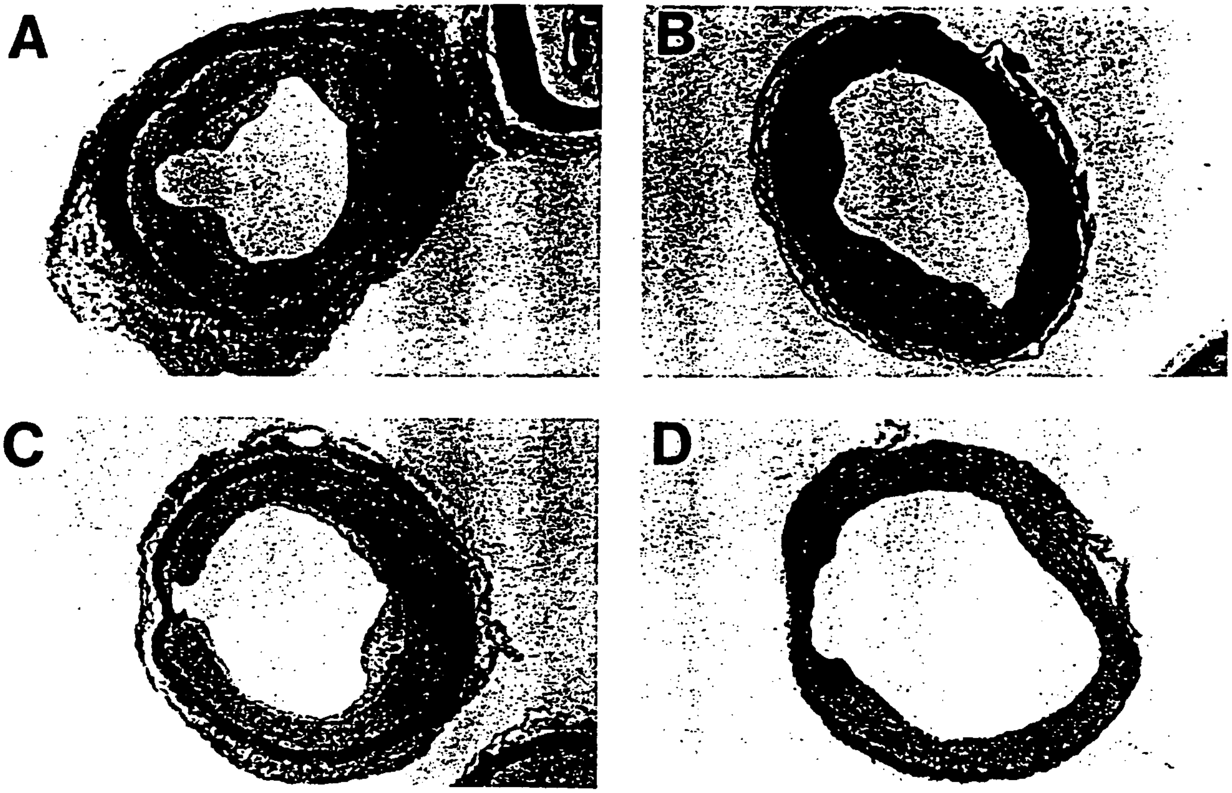

Fig. 3. Histologic section from the 3 day follow-up group. A: Cut extended throughout the plaque into the inner one-third of the media. B: Cut extended throughout the plaque leaving internal elastic membrane intact behind. C,D: Cuts in nondiseased artery. There is no visible injury at the point where the anchoring wire was deployed.

with intramuscular ketamine 20 mg/kg, acepromazine 1 mg/kg, and atropine 1 mg/kg. Anesthesia was maintained with 1–5% halothane and oxygen via a standard 8F endotracheal tube. The left carotid artery was isolated and a 9F hemostatic sheath (USCI) was inserted. The animal then received IV heparin 200 units/kg and ampicillin 250 mg.

A 9F hockey stick guide catheter was introduced selectively in the right and left external iliac arteries and baseline angiography was performed. A peripheral angioplasty balloon, 3 cm in length and 6–8 mm in diameter, was advanced over a 0.035 inch guidewire into the proximal segment of the right external iliac artery. The balloon was custom-modified with a single linear array of eight holes of 50 μm diameter along the length of the balloon. After positioning, the balloon was inflated with 4 ml of 0.3% hydrogen peroxide at a pressure of 6 atmospheres. The rationale for directional injection of hydrogen peroxide through a perforated balloon was to produce an eccentric lesion with morphology suitable for atherectomy. Next, this balloon was exchanged for a regular peripheral angioplasty balloon oversized by ≥1.3 times the artery diameter and advanced into the right distal external iliac artery. Inflation to 6 atmospheres for 60 sec was carried out. The rationale for this balloon injury was to produce a concentric lesion for subsequent evaluation of the Omnicath® atherectomy catheter. The procedure was repeated for the left external iliac artery. The catheter and sheath were then removed and the carotid artery was ligated. The wound was repaired and the animal was allowed to recover. Ampicillin 250 mg orally was given 3 times daily for 5 days. The animals remained on the atherogenic diet for the following 8 weeks and then underwent atherectomy.

Atherectomy

Sedation and anesthesia were performed as described above. The right carotid artery was isolated and a 9F hemostatic sheath was inserted. Baseline angiography was performed as described above. The Omnicath® was advanced over a 0.014 or 0.018 inch guidewire. The atherectomy was performed in the proximal and distal segments of the right and left external iliac arteries at the site of the prior arterial balloon injury. After placement

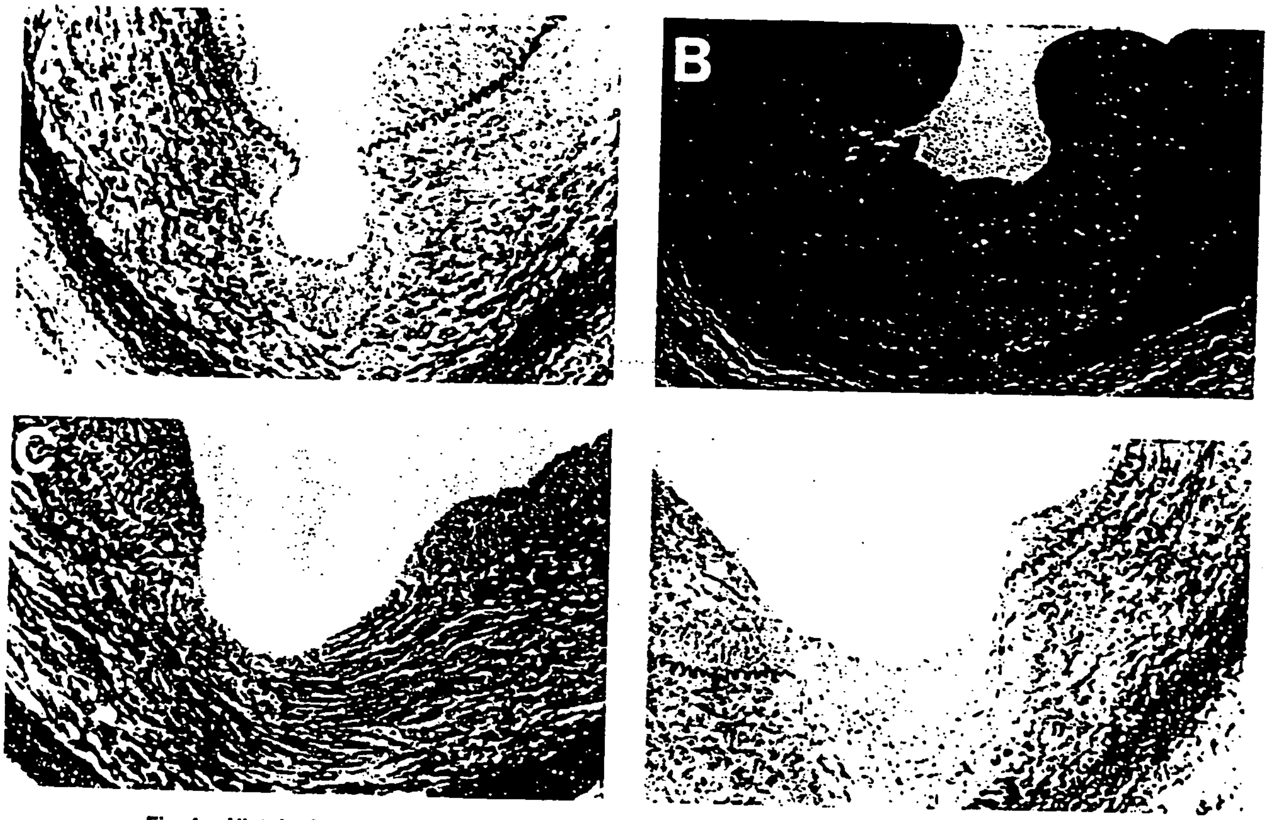

Fig. 4. Histologic sections at 6 week follow-up. B and D demonstrate filling of the atherectomy cut with proliferating smooth muscle cells up to the internal elastic lamina. A and C show only partial filling of atherectomy sites when the cut extended deeper into the media.

at the proper segment, the positioning of the Omnicath® cutting window was determined by fluoroscopic appearance and by a radiopaque marker dot on the housing just distal to the cutting window. The deflector anchoring wires were deployed to the depth desired and stable, anchored position was assured by a gentle tug on the catheter (Fig. 2). Suction was started and the cutter activated then passed across the window. The cutter was then stopped, suction was discontinued, and the anchoring wires were retracted. Additional cuts were made after repositioning the cutting window. The tissue collected in the filter during the procedure was fixed in zinc formalin and submitted for pathologic examination. After atherectomy, the catheter and sheath were removed and the wound was repaired. The two consecutive procedures (lesion induction and atherectomy) resulted in bilateral carotid ligation. In the swine, a well-developed vertebrobasilar system fully compensates for the bilateral carotid ligation. Three days after atherectomy, five animals were sacrificed by exsanguination under deep anesthesia. Both external iliac arteries were harvested for pathologic examination. The other five animals remained on the atherogenic diet for 6 weeks and underwent angiography prior to sacrifice as described above. Both external iliac arteries were harvested for pathologic examination.

RESULTS

The hydrogen peroxide induced lesion in the proximal segment of the external iliac artery was eccentric in morphology and consisted of smooth muscle cells, monocytes, and multiple foam cells surrounding the necrotic core. The luminal narrowing was in the range of 20% to 70%. The balloon overstretch injury in the distal segment of the external iliac artery resulted in minimal (less than 15% of the total arterial lumen) circumferential neointimal proliferation composed mainly of smooth muscle cells.

The 3 day post-atherectomy histologic sections (Fig. 3) demonstrated cut depths varying from partial plaque removal (first and second degrees of extension) to near full thickness of the arterial wall (third and fourth degrees of extension), depending on the presence of neointimal proliferation at the atherectomy site and depth of atherectomy chosen by various deflections of the anchoring wire. There was no visible injury to the opposite wall

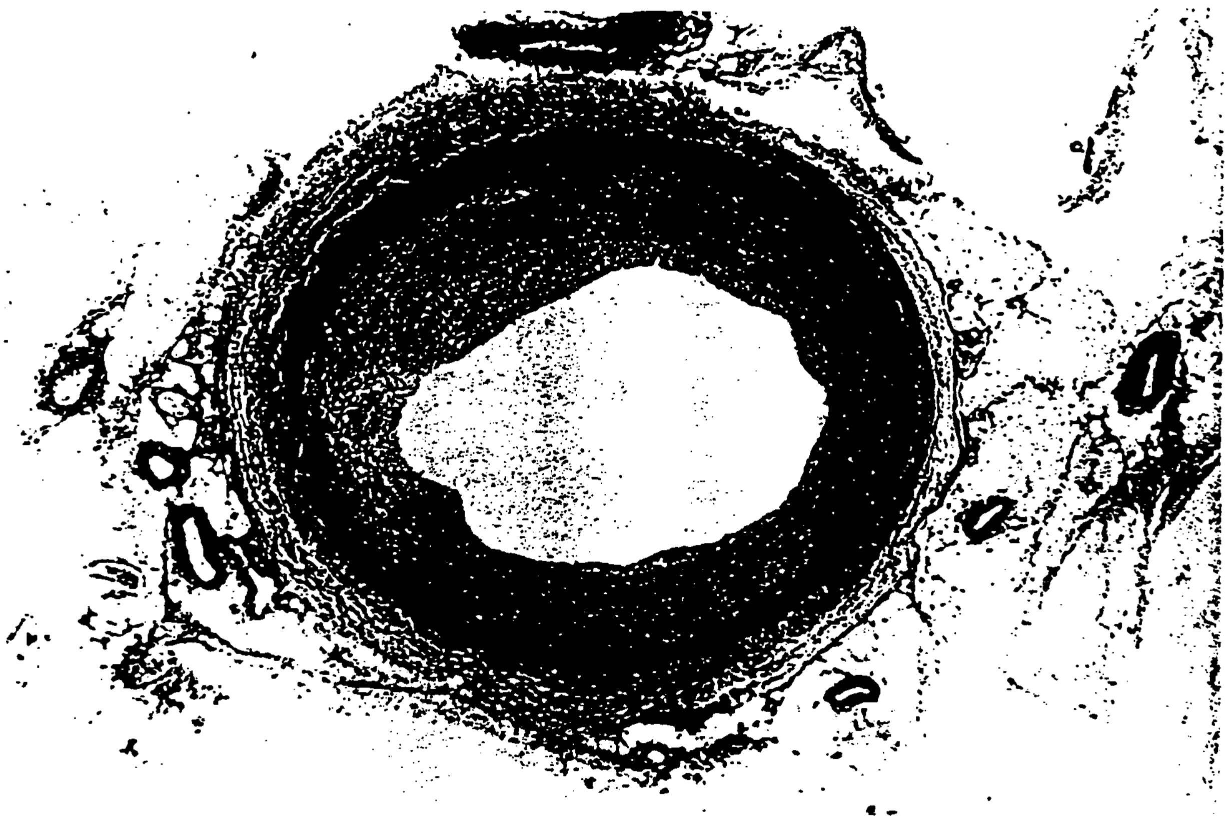

Fig. 5. Six week follow-up histology shows no significant neointimal proliferation at the points where the anchoring wire was deployed.

imposed by the deflected anchoring wires, even when the deflection was maximal.

The depth of atherectomy was controlled by angiographically sizing the vessel prior to atherectomy and choosing levels 1–4 degrees of deflection of the anchoring wires. The removed tissue was collected on a filter during the procedure and subsequently underwent histologic examination which revealed in most instances neointimal tissue alone (first degree of extension), neointimal tissue with underlying internal elastic lamina (second degree of extension), or neointimal tissue and internal elastic lamina with underlying media (third and fourth degrees of extension).

The histologic sections of the 6 week follow-up group (Fig. 4) demonstrated minimal healing response. We observed either filling of the defect to the level of the internal elastic lamina (Fig. 4B,D) or partial filling (Fig. 4A,C), especially when the cut removed a considerable amount of the media. The tissue directly beneath the Omnicath®-imposed filling defect consisted of smooth muscle cells and collagen matrix. The collagen matrix was present deeper in the media, close to the external elastic membrane, and the smooth muscle cells were closer to the luminal surface and appeared to be growing at right angles to the smooth muscle cells at the edge of the lesion. There was no significant neointimal proliferation at the points where the anchoring wire was deployed (Fig. 5).

Angiographic Results

The immediate post-atherectomy angiography revealed spasm at the atherectomy site in the majority of animals. Dissection was observed in one animal. There was no significant lumen renarrowing in nine of ten arteries analyzed in the 6 week follow-up angiography. One artery showed approximately 20% luminal narrowing 6 weeks after atherectomy.

Procedure Related Complications

In one animal a confined dissection was caused by the Omnicath®, as mentioned above. The pathology results demonstrated a profound cut extending throughout the media to the adventitia in a plaque free area. There were no vascular perforations in the total of 40 cuts performed.

DISCUSSION

The Omnicath® device permitted safe, controlled atherectomy in this investigative model. The potential advantages of this catheter system are regulation of the depth of the cut, continuous debris removal from the operative site (decreasing the possibility of distal embolization), and a nontraumatizing anchor system which permits distal perfusion during atherectomy. The Omnicath® suction port removed only 2–3 ml of blood per cut, a negligible volume compared to the transluminal extraction catheter [1]. The anchoring wire system does not appear to overstretch the artery, so the immediate effect is based solely on the atherectomy and not on combined atherectomy and balloon dilatation effect as in balloon supported atherectomy catheters. This is confirmed by the histologic studies which showed no signs of intimal or medial reaction to the anchoring wires after either short (3 days) or longer (6 weeks) follow-up periods. While maintaining distal perfusion may be of little importance in the peripheral vasculature, this feature may be particularly useful during intracoronary intervention. Studies utilizing a 4.7F design of the Omnicath® in the coronary circulation of this porcine model are now underway.

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Omnicath® is a product of American BioMed Inc. and is protected by the following US patents: US 4994067, US 4850957, US 5087265.

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